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FROMMER LAWRENCE & HAUG LLP			WHITEMAN, BRIAN A	
745 Fifth Avenue New York, NY 10151			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/245,603	CURIEL ET AL.				
Office Action Summary	Examiner	Art Unit				
	Brian Whiteman	1635				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	I36(a). In no event, however, may a reply be timely within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. O (35 U S C & 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>17 F</u>	ebruary 2005.	,				
2a) ☐ This action is FINAL . 2b) ☑ This	s action is non-final.					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims	=x parte Quayle, 1955 C.D. 11, 45	33 O.G. 213.				
 4) Claim(s) 1-4,9,11,16,22,23 and 26-29 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-4,9,11,16,22,23,26-29 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 						
Application Papers						
9)☐ The specification is objected to by the Examine	er.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11104 S. Retent and Indemset Office.						

DETAILED ACTION

Non-Final Rejection

Claims 1-4, 9, 11, 16, 22, 23 and 26-29 are pending.

Applicant's traversal, the amendment to the specification, the new sequence listing, the amendment to claims 1, 16, and 22, and the addition of claims 26-29 in paper filed on 2/17/05 is acknowledged and considered.

Claim Objections

Claim 29 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 27. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9, 11, 16, 22, 23, and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation 'linearized at a nucleotide restriction site in the mutated fiber gene' in amended claims 1, 16, and 22 and claims dependent therefrom is not supported by the as-filed specification. There appears to be a lack of written description of the limitation in the application as filed. See MPEP § 2163.06. Applicants assert that pages 72, lines 12-21 and 73, lines 1-13 and Figure 5 provide support for the limitation. Page 72, lines 12-21 and 73, 1-13 recite:

To reduce the nonrecombinant background generated by pTG3602, prior to transformation this plasmid was cleaved with a restriction enzyme within or near the region of the genome where the final construct was going to be inserted. Although this method has numerous advantages compared to traditional generation of recombination adenovirus genomes in mammalian cells, it requires the existence of unique restriction sites within the regions of the adenovirus genome to be modified. However, Ad5 genomic DNA in p1G3602 does not contain any unique restriction sites in the fiber gene, which limits its utility for modifications of fiber. Thus, to overcome this limitation, this plasmid was modified by inserting a unique cleavage site for the restriction endonuclease Swal into the fiber gene. To this end, one of the two Ndel sites present in Ad5 DNA and localized 47 bp downstream from the fiber gene's 5' end was converted into Swal site by insertion of an Swal-linker (Figure 5). The plasmid generated, pVK50, was then recombination with the fragment of DNA utilized for homologous containing the gene encoding fiber-FLAG flanked with viral DNA adjacent to the fiber gene in the Ad5

genome. As a result of this recombination, a plasmid, pVK300, containing a modified fiber gene in the context of the complete adenovirus genome was derived. Adenovirus DNA was released from pVK300 by Pacl digestion and used for transfection of 293 cells to rescue the virus as described (7).

In addition, Figure 5 only provides support for a SwaI site in the fiber gene of a plasmid comprising Ad5 DNA. Pages 72 and 73 and Figure 5 only disclose inserting a SwaI restriction site into the fiber gene. The claims are broader than the teaching in the specification directed to linearized at a SwaI restriction site in the mutated fiber gene. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

In addition, the limitation 'wherein said nucleotide restriction site is defined by the nucleotide sequence 5'ATTTAAAT3'' in new claims 26, 27, and 29 is not supported by the asfiled specification. There appears to be a lack of written description of the limitation in the application as filed. See MPEP § 2163.06. Applicants have not cited where the new claims 26, 27, and 29 are supported by the instant specification. The examiner has thoroughly searched the instant specification and cannot found support for the new claims 26, 27, and 29.

In addition, the limitation 'homologous recombination in a bacterium between a plasmid comprising an adenovirus with a mutated fiber gene linearized at a nucleotide restriction site in the mutated fiber gene and a plasmid comprising a cDNA encoding the modified fiber comprising a tripeptide having the sequence Arg-Gly-Asp (RGD) into the HI loop domain of the

fiber knob' in new claims 28 and 29 is not supported by the as-filed specification. There appears to be a lack of written description of the limitation in the application as filed. See MPEP § 2163.06. Applicants have not cited where the new claims 28 and 29 are supported by the instant specification. The examiner has thoroughly searched the instant specification and cannot found support for the new claims 28 and 29.

Thus, nothing in the specification would lead one to the particular limitations set forth in the amended claims 1, 16, and 22 and claims dependent therefrom and new claims 26-29 set forth in the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 16, 22, 23, 27, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: introducing the adenovirus to primary tumor cells in vitro or ex vivo. The claim is missing an active step to complete the pre-amble of the claim.

Claims 22, 23, 27 and 29 are rejected under 112 second paragraph because they are dependent on claim 16.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention

thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The instant claims read on a recombinant adenovirus (replication competent or replication defective) comprising a modified fiber comprising a tripeptide RGD in any part of the HI loop domain of the fiber knob and methods of using the recombinant adenovirus. The product claims read on a product by process. The process recited in the claims involves homologous recombination between a plasmid comprising adenovirus DNA with a mutated fiber gene (e.g., a unique restriction site was placed into a region of the fiber gene) and a plasmid comprising a cDNA encoding a modified fiber comprising a tripeptide having the sequence RGD in the HI loop domain of the fiber knob. The process would not be expected to impart distinctive structural characteristics to the claimed product (recombinant adenovirus) because the claims

only require that the recombinant adenovirus comprise a modified fiber gene encoding a tripeptide having the sequence RGD in the HI loop domain of the fiber knob. See MPEP 2113. Thus, the process does not distinguish the claimed adenovirus in the instant claims over any prior art teaching a recombinant adenovirus comprising a RGD motif in the HI loop domain of the fiber knob.

In addition, the limitation "that mediates enhanced gene transfer to primary tumor cells" in the instant claims does not have patentable weight over the prior art because the limitation does not disclosed a structural feature of the adenovirus that would distinguished from the prior art. See MPEP 2111.02. In addition, instant claims 1-4, 9, 26, and 28-29 are product claims and not method claims.

Claims 1-4, 9, and 11 remain and claim 28 is rejected under 35 U.S.C. 102(e) as being anticipated by Wickham et al. (US 5,846,782). The previous rejection is maintained for the reasons of record advanced on pages 3-5 of the Office action mailed on 2/26/03.

Applicant's arguments filed 2/17/05 have been fully considered but they are not persuasive. Applicant's argue that Wickham does not teach or suggest generating a fiber gene modified by homologous recombination between a plasmid comprising an adenovirus with a mutated fiber gene linearized at a nucleotide restriction site in the mutated fiber gene and a plasmid comprising a cDNA encoding the modified fiber comprising a tripeptide having the sequence Arg-Gly-Asp (RGD) into the HI loop domain of the fiber knob.

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Applicant's argument is not found persuasive because the claims are directed to an old product and not a method of producing the old product (producing the claimed adenovirus using homologous recombination). See MPEP 2113, which recites:

Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983).

This is the case here because the instant claims do not recite any structural limitation that would indicate that the claimed adenovirus is structurally different than the recombination adenovirus taught by Wickham. The claims do not recite where the RGD is inserted into the HI loop of the fiber knob. The claimed product embraces a recombinant adenovirus comprising a modified fiber protein comprising the tripeptide (RGD) in the HI loop domain of the fiber knob. The only difference between the claimed product and the product taught by Wickham is how the product is produced. Wickham teaches a method of ligating DNA encoding the RGD motif into the fiber knob of the claimed recombinant adenovirus and the instant specification teaches using homologous recombination to produce the claimed recombinant adenovirus.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wickham et al. 1 (WO 96/26281, cited on a PTO-1449) taken with Wickham et al. 2 (US 5,846,782).

Wickham teaches incorporating a non-native binding domain (RGD peptide) within an exposed loop of a mutant adenovirus to create a fiber chimera and producing recombinant adenovirus comprising the fiber chimera and (page 25). Wickham teaches the limitation in

instant claim 4 (pages 9 and 16). However, Wickham et al. 1 does not specifically teach that the exposed loop of the adenovirus is the HI loop of the fiber knob.

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However, at the time the invention was made, Wickham et al. 2 teaches producing adenoviruses comprising a modified fiber protein containing an RGD motif (columns 20-21). Wickham et al. 2 teach that the exposed loop is preferably the HI loop of the fiber knob (columns 20-21). Accordingly, in view of the prior art represented by Wickham et al. 1 and 2, one of ordinary skill in the art would have had sufficient motivation to produce recombinant adenoviruses containing a RGD motif in the HI loop domain of the fiber knob with a reasonable expectation of success.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Wickham et al. 1 taken with Wickham et al. 2, namely to insert an RGD motif into the HI loop domain of the fiber knob of a recombinant adenovirus. One of ordinary skill in the art would have been motivated to combine the teaching because Wickham et al. 2 teaches that the adenovirus is more efficient for entry into cells compared to an adenovirus with a wild-type fiber protein.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments with respect to claims 1, 4, and 28 have been considered but are most in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 9, 11, and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 12 of U.S. Patent No. 6,824,771. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims from '771 embraced a recombinant adenovirus having a modified fiber protein containing RGD in the HI loop domain of the fiber knob. The instant claims are directed to a recombinant adenovirus comprising a modified fiber gene, wherein the modified fiber gene comprises a cDNA encoding a tripeptide having the sequence RGD in the HI loop domain of the fiber knob and using the adenovirus in a method of killing tumor cells.

The claims from '771 are directed to using a conditionally replicative adenovirus in a method treating tumors in a subject, wherein the fiber gene encodes a cDNA encoding a tripeptide having the RGD motif in the HI loop domain of the fiber knob. The instant claims embrace a replication competent or replication defective adenovirus comprising a RGD motif in the HI loop domain of the fiber knob. However, the claims from '771 do not specifically recite the limitation in instant claims 4, 9, and 11. In addition, the claims from '771 do not specifically recite making the recombinant adenovirus using homologous recombination as recited in instant

claims 1 and in a bacterium in instant claim 28. However, the product- by-process claims do not provide a distinguishable structural feature of the product to distinguish the claimed adenovirus in the instant application over the adenovirus in claims of '711. See MPEP 2113. In addition, the limitation in instant claim 4 would be an obvious variant of the claims 1 and 2 from '771 because the fiber knob of the adenovirus would have to be able trimerize and retain its biosynthesis profile for the adenovirus to infect tumor cells. The limitation in instant claim 9 and instant claim 11 would be obvious variants of claims 1 and 12 from '771 in light of the specification of '771 teaching using a nucleotide sequence encoding a thymidine kinase as the exogenous nucleotide sequence in claim 12 of '771. See Figure 2 of '771. Therefore, the claims of the instant application and US patent '771 are obvious variants of one another.

Claims 1, 2, 4, 9, 11, and 28 are directed to an invention not patentably distinct from claims 1, 2, and 12 of commonly assigned US Patent 6,824,771. Specifically, for the reasons set forth under the double patenting heading.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US patent '771, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting

inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Response to Arguments

Applicant's arguments, see page 8, filed 2/17/05, with respect to the rejection(s) of claim(s) 1-4, 9, 11, 16, and 23 under 112 first paragraph new matter have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment to claims 1, 16, and 22 and addition of new claims 26-29. See new matter rejection under 112 first paragraph.

Applicant's arguments, see page 9, filed 2/17/05, with respect to the rejection of claims 1-4, 9, 11, 16, and 22-25 under 112 second paragraph rejection have been fully considered and are persuasive. The rejection of claims 1-4, 9, 11, 16, 22-25 has been withdrawn. However, upon further consideration, a new ground of rejection is made against claim 16 and claims dependent therefrom. See new 112 second paragraph rejection.

Applicant's arguments, see page 8, filed 2/17/05, with respect to the objection to the specification have been fully considered and are persuasive. The objection of the specification has been withdrawn.

Applicant's arguments, see pages 11 and 12, filed 2/17/05, with respect to the 103(a) rejection to claims 16 and 22-23 have been fully considered and are persuasive. The rejection of claims 16 and 22 and 23 has been withdrawn because of the amendment to the claim to recite the

method step of homologous recombination to produce the adenovirus.

Conclusion

It is noted that applicants requested an interview in the response filed on 2/17/05. The examiner contacted the attorney of record and discussed having the interview after the instant office action is received and reviewed by attorney of record because of the new rejections under 112 first paragraph and double patenting. See Interview summary 4/26/05.

Wickham et al. (Journal of Virology, 71: 8221-8229, 1997) is cited on a PTO-892 because Wickham et al. teach recombinant Ad containing fibers with targeting ligands (RGD motif) positioned at the carboxy terminus of the fiber molecule. However, it is not apparent if positioning an RGD motif at the carboxy terminus of the fiber molecule as taught by Wickham et al. reads on inserting a tripeptide having the sequence RGD into the HI loop domain of the fiber knob of an adenovirus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

Patent Examiner, Group 1635

Buir & Ateman